

REMARKS

Applicant appreciates the Examiner's thorough review of the present application, and respectfully requests reconsideration in light of the preceding amendments and the following remarks.

Claims 1-30 are pending in the application. The original claims have been amended to better define the claimed invention. New claims 27-30 have been added to provide Applicants with the scope of protection to which they are believed entitled. Support for the amendments is explained in attached *Appendix*. No new matter has been introduced through the foregoing amendments.

Claim Rejections under 35 USC § 112

Applicant respectfully submits that the amended claims overcome the rejections under 35 USC § 112.

Claim Rejections under 35 USC § 102

Original claims 1-21 are rejected as being anticipated by US 4,973,301 to *Nissenkom*. According to the Examiner, Figs. 3, 4 of the reference disclose an elongated tube wherein the proximal end of the tube has a funnel-like shape and wherein the funnel comprises at least one slit which enables suturing of the stent to the duct. Although Applicant does not necessarily agree with the Examiner's position, amendments have nevertheless been made to define the claimed invention over the art.

In particular, amended claim 1 now recites a stent for use in the oral cavity, said stent being an elongate member and comprising: an enlarged proximal portion at a proximal end of the stent; and a bore extending through said stent from said proximal end to a distal end of the stent; said enlarged proximal portion comprising: a proximal rim adapted for being located adjacent an oral cavity; and at least one aperture other than said bore, radially inwardly spaced from said rim, and adapted for suturing said stent to said oral cavity, in use. The other independent claims have been amended in a similar manner.

First, Applicant respectfully submits that the cited reference is not a proper reference. The reference is directed to a catheter for use in an intra-urethral duct, for providing communication between the bladder cavity and the outside of the body, enabling urine accumulated in the bladder to be discharged therefrom directly to outside of the body. The *Nissenkom* catheter has to withstand the high closing periodic pressure voluntarily or involuntarily applied by the surrounding sphincters.

In contrast, the claimed invention relates to a stent for use in a very different part of the body, i.e., the oral cavity. In particular, the claimed stent permits drainage of saliva from the salivary gland, which is very different both physiologically (for example, the salivary gland does not comprise a holding volume for storing saliva parallel to the bladder, which is a holding volume for urine) and functionally (i.e., there is no controllable muscle for discharging saliva from such a volume at will parallel to the urethral sphincter) from the bladder, to the oral cavity, which is still inside the body. Accordingly, a person of ordinary skill in the art would not consider IU catheters when seeking to improve a condition relating to the oral cavity or salivary glands.

Second, even if the reference were to be properly citable against the claims of the instant application, it clearly does not anticipate the current claims.

In amended claim 1, the enlarged portion is at a proximal portion of the stent, i.e., closest to the point of discharge within the oral cavity. In the *Nissenkom* reference, the “funnel like portion” is at a distal end of the IU catheter, i.e., furthest away from the discharge point in the urethra.

Further, in amended claim 1, the enlarged portion has at least one aperture, spaced inwardly from the rim. The enlarged portion of the claimed invention “is adapted for being located adjacent the oral cavity” and allows the stent to remain stably in place without normally being further inserted into the salivary duct. The claimed aperture(s), which is/are inwardly spaced from the rim and provided on the enlarged portion allows the stent to be sutured to the oral cavity in a simple and straightforward manner.

In contrast, the “funnel-like portion” of the cited reference is not adapted for being located adjacent the oral cavity. If it is to be used in a distal manner (following the orientation

taught by the *Nissenkom* reference, if the teachings were applied to the oral cavity), it would sit at the distal end of the salivary gland. If, on the other hand, the teaching of the *Nissenkom* reference were reversed, with the catheter of the reference inverted and placed at the proximal end, the sharp edges formed by the slits of the “funnel” of the reference would make it supremely unsuitable for location in the oral cavity. In either position, the “funnel like portion” would damage the tissues adjacent thereto. Thus, not only is the device disclosed in Figs. 3, 4 of the *Nissenkom* reference not adapted for use with respect to salivary glands or the oral cavity in general, it actually teaches away therefrom by virtue of the potential damage that may be caused therat.

Furthermore, the “funnel like portion” of the *Nissenkom* reference comprises slits that extend to the distal edge of the “funnel like portion”. In contrast, the claimed invention includes aperture(s) that is/are inwardly spaced from the proximal rim of the enlarged portion. Thus, the applied reference does not teach or suggest all features of the now claimed invention, and the 102 rejection should be withdrawn.

Of particular note, contrary to the Examiner’s allegation, the slits 12’ of *Nissenkom* are *not* adapted for suturing a catheter to the oral cavity. The slits are V-shaped and formed between strips which are each of substantially uniform cross-section. This configuration makes it exceedingly difficult, if not impossible, to suture the IU catheter, as the suturing thread would tend to slip out of the open ends of the strips. Such an inconvenient and unsuitable arrangement would have led a person of ordinary skill in the art away from even considering that such an arrangement may be used for suturing the *Nissenkom* IU catheter. Furthermore, it should be noted that, as shown in Fig. 4 of the reference, the slits 12’ are adapted for being placed *inside* the bladder, and are totally unreachable for suturing. Accordingly, Applicant respectfully submits that there is absolutely no motivation for a person of ordinary skill in the art to consider such slits for suturing.

The amended independent claims are therefore patentable over the applied reference. The dependent claims are considered patentable at least for the reason advanced with respect to the respective amended independent claims.

Regarding claim 4, the cited reference, in particular Figs. 3 and 4, does not teach or disclose a proximal funnel-like portion but rather a plurality of flared out strips at the distal portion, and there is no continuous rim. Furthermore, the reference teaches away from claim 4, as it would be nearly impossible, quite aside from causing damage and being immensely painful, to insert a tube with a distal facing funnel through the urethra and into the bladder, and also difficult to remove it therefrom. Regarding item 36 in Fig. 5C, this is an IU catheter holder, and not a catheter, and, moreover, it does not comprise apertures for suturing the same. Furthermore, such IU catheters are not sutured at all to the penis, and there is no suggestion in the *Nissenkom* reference for doing so. Thus, claim 4 is neither disclosed nor suggested by the reference.

Regarding claims 16 to 19, the claim features are not disclosed nor suggested in the reference.

Similarly, there is no disclosure or suggestion of the stent disclosed in claim 21, and the method claims 22-29 which have been amended to remove multiple dependency.

Accordingly, it is respectfully submitted that the pending claims are patentably distinguishable from the cited reference.

Each of the Examiner's rejections has been traversed. Accordingly, Applicants respectfully submit that all claims are now in condition for allowance. Early and favorable indication of allowance is courteously solicited.

The Examiner is invited to telephone the undersigned, Applicant's attorney of record, to facilitate advancement of the present application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 07-1337 and please credit any excess fees to such deposit account.

Respectfully submitted,

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Appendix

Support for claim amendments

Claim 1: page 10, line 9; original claim 1; Figs 1A, 1A; page 8, lines 26, 27; page 9, lines 1-10.

Claim 2: original claim 2; page 9, lines 2, 22.

Claim 3: original claim 3; Fig. 1A.

Claim 4: original claim 1; Fig. 1B.

Claim 5: Fig. 2A.

Claims 6 to 12: original claims 6 to 12.

Claim 13: original claims 1, 14.

Claim 14: original claim 14.

Claim 15: original claim 15; page 6, 18-25.

Claims 16 to 19: original claims 16 to 19.

Claim 20: page 10, lines 16-20; Figs. 3A to 4D.

Claim 21: amended claims 1, 4; Figs. 2B, 2C.

Claim 22: original claim 22, amended claim 1.

Claim 23: page 10, lines 16-20; Figs. 3A to 4D.

Claims 24 to 26: original claims 24 to 26.

Claim 27: page 10, lines 1-3.

Claim 28: page 6, lines 21-25.

Claim 29: original claims 16 to 19.

Claim 30: page 6, lines 4 to 7.